

EXHIBIT B

SECOND AMENDED COMPLAINT

**Filed on or About
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CARLOS JUENKE
CLERK U.S. DIST. CT.
S.D. OF FLA.-MIAMI

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Plaintiff,

CIVIL ACTION NO.95-1354-CIV-MARCUS

FILED IN CAMERA AND UNDER SEAL

**SECOND AMENDED COMPLAINT
For Money Damages and Civil
Penalties Under the False Claims Act
31 U.S.C. §§3729-3732**

SECOND AMENDED COMPLAINT
FOR MONEY DAMAGES AND CIVIL PENALTIES UNDER THE FALSE
CLAIMS ACT 31 U.S.C. §§3729-3732

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[REDACTED]

[REDACTED] The false and fraudulent price and cost records and statements were knowingly reported and used by the Defendants in a manner whereby they were relied upon by the United States Medicare Program and by federally funded States' Medicaid Programs paying claims for the pharmaceuticals specified herein sold by the DEFENDANT PHARMACEUTICAL MANUFACTURERS. As a direct and proximate result of the false and fraudulent price and cost records and statements made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS, the Medicare and Medicaid programs paid and approved claims for the pharmaceuticals specified herein of the DEFENDANT PHARMACEUTICAL MANUFACTURERS in amounts that grossly and materially exceeded the reasonable payment amount for such pharmaceuticals permitted by the applicable federal law. The claims for payment in grossly excessive amounts were false claims because they were based on false and fraudulent price and cost records and statements made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and because they were for amounts that materially exceeded the reasonable amount permitted to be paid under applicable law. The claims were fraudulent claims because they were paid in such excessive amounts only because of the falsely inflated price and cost records and statements knowingly made and used by the DEFENDANT PHARMACEUTICAL MANUFACTURERS. The Defendants' false reports of price and cost information

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constituted false statements and/or records that were made and used for the purpose of getting false or fraudulent claims approved or paid.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

By falsely representing their price and cost information, the DEFENDANT PHARMACEUTICAL MANUFACTURERS induced the UNITED STATES and States' Governments to pay exorbitant and unreasonable sums of money to the customers of the DEFENDANT PHARMACEUTICAL MANUFACTURERS to which they were not entitled and which induced them to utilize more of the specified drugs to obtain greater excessive profits.

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The DEFENDANT PHARMACEUTICAL MANUFACTURERS knew or should have known that their false and fraudulent representations of prices and costs would cause the Medicare and States' Medicaid programs to pay grossly excessive and unreasonable amounts of money for claims for their pharmaceutical products and that said payments would, in significant part, be made by the United States Government. The United States has sustained damages as a result of the false and fraudulent representations of prices and costs knowingly made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS. Accordingly, the United States Government is entitled to recover treble damages, plus civil penalties and costs in excess of ONE HUNDRED BILLION AND 00/100 DOLLARS (\$100,000,000,000.00) pursuant to **31 U.S.C. §3729, et. seq.**

SECTION NO. 2

THE PARTIES

2. The Plaintiff in this action is the UNITED STATES. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), and The Bureau of Program Operations ("BPO") were agencies and instrumentalities of the UNITED STATES and their activities, operations and contracts in administering the Medicare program were paid from UNITED STATES' funds. The UNITED STATES and its subcontractors performing on behalf of the UNITED STATES provided Medicare benefits to qualified beneficiaries which included payment of claims for the pharmaceuticals specified herein manufactured by the

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DEFENDANT PHARMACEUTICAL MANUFACTURERS and relied upon the false and fraudulent price and cost representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS in approving and paying claims.

3. The States, United States Territories, and the District of Columbia provided Medicaid benefits to qualified beneficiaries which included payment of claims for the pharmaceuticals specified herein manufactured by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and relied upon the false and fraudulent price and cost representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS in approving and paying claims. A significant part of said Medicaid reimbursement was paid from United States Government funds pursuant to **42 U.S.C. § 1396(b)**.

4. The Relator, VEN-A-CARE, is a corporation organized under the laws of the State of Florida, with its principal offices in Key West, Florida. The Relator's principal officers and directors include Zachary T. Bentley and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The Relator is an infusion pharmacy and provides pharmaceuticals, such as the intravenous, injectable [REDACTED] [REDACTED] specified in this Second Amended Complaint, as a Medicare Part B supplier and as a Florida Medicaid provider. The Relator has direct and independent knowledge of the information, and is the "original source" of the information on which these allegations are based within the meaning of **31 U.S.C. §3730(e)(4)(A) and (B)**. The Relator has standing to bring this action pursuant to **31 U.S.C. §3730(b)(1)**. The information upon which these allegations are based was voluntarily provided by the Relator to the Federal

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Government beginning in 1991 and thereafter has been frequently supplemented by the Relator.

5. The Defendant, ABBOTT LABORATORIES ("ABBOTT"), is a corporation organized under the laws of Illinois with its principal offices in Abbott Park, Illinois. At all times material to this civil action, ABBOTT has transacted business in the Federal Judicial District of the Southern District of Florida by, including but not limited to, selling and distributing pharmaceutical products to purchasers within the Southern District of Florida.

6. [REDACTED]

7. [REDACTED]

8. [REDACTED]

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**PAGES 9 THROUGH 13
HAVE BEEN COMPLETELY REDACTED
WHICH INCLUDES
PARAGRAPHS 9 THROUGH 26**

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[REDACTED]

27. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

28. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

29. The Defendants specified in paragraphs 5 through 28 are sometimes referred to herein collectively as the "DEFENDANT PHARMACEUTICAL MANUFACTURERS". Any and all acts alleged herein to have been committed by any or all of the DEFENDANT PHARMACEUTICAL MANUFACTURERS were committed by said Defendant's officers, directors, employees, or agents who at all times acted on behalf of their respective DEFENDANT DRUG MANUFACTURER.

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SECTION NO. 3

JURISDICTION & VENUE

30. Jurisdiction is founded upon the **Federal False Claims Act, (the "Act")** 31 **U.S.C. §3729-32**, specifically **31 U.S.C. §3732**, and also **28 U.S.C. §§1331, 1345**.

31. The Federal False Claims Act reaches the type of fraudulent activity alleged herein in accordance with the express language of the Act as well as precedents arising from applications of the present Federal False Claims Act and earlier versions, United States v. Neifert-White Company, 390 U.S. 228; 88 S.Ct. 959 (1968). Specifically, the United States Supreme Court's application of the Act in Neifert-White applies to this case as follows:

A. ". . . the Act was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." 88 S.Ct., at 961.

B. The Act applies to the conduct of a Defendant manufacturer that supplies falsely inflated price information in support of a customer's claim. 88 S.Ct., at 960.

C. The Act applies even where the price information supplied by the Defendant manufacturer is inflated by only approximately 25% over the truthful price. 88 S.Ct., at 960.

D. The Act applies even though the Defendant manufacturers did not submit the false price information directly to the Government and received no payment of funds from the Government.

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E. The Act applies even though the inflated portion of the price was received by customers of the Defendant manufacturers who are not parties to the case. 88 S.Ct., at 960.

32. Venue in the Southern District of Florida is appropriate under **31 U.S.C. §3732(a)** and sufficient contacts exist for jurisdiction in that each of the DEFENDANT PHARMACEUTICAL MANUFACTURERS transacted business in the Southern District of Florida by selling directly or through wholesalers their pharmaceutical products in the Southern District of Florida which the respective Defendants knew would be supplied to Medicare beneficiaries and Medicaid recipients and for which the DEFENDANT PHARMACEUTICAL MANUFACTURERS knew that grossly excessive and unreasonable payments for claims would be made to the providers/suppliers by the Medicare and Medicaid programs.

33. A copy of the initial Complaint and Amended Complaints and written disclosure of substantially all material evidence and information VEN-A-CARE possesses were served on the Government pursuant to Rule 4(d)(I), Fed.R.Civ.P., prior to the filing of the initial and Amended Complaints in camera and under seal by delivering a copy of the summons, Complaints, material evidence and information to the United States Attorney for the Southern District of Florida and by sending a copy of the summons, Complaints, material evidence and information by certified mail to the Attorney General of the United States at Washington, District of Columbia. Thereafter the Relator has continued its investigation of the matters herein and has diligently and expeditiously provided any and

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all documentary and other evidence to the Office of the Attorney General of the United States and to the Office of the United States Attorney for the Southern District of Florida prior to filing this Second Amended Complaint. A copy of the Second Amended Complaint was served in the manner required by law, on the Attorney General and on the United States Attorney for the Southern District of Florida prior to filing with the Court.

34. The Relator alleges: (A) that no allegation or transaction of defrauding the United States was made prior to the filing of the Complaints in public disclosures regarding the subject matter herein against any of the DEFENDANT PHARMACEUTICAL MANUFACTURERS; (B) that none of the DEFENDANT PHARMACEUTICAL MANUFACTURERS was named in public disclosures made prior to the filing of the Complaints regarding the subject matter herein; and (C), if the Court makes a finding against the Relator as to the allegations set forth in (A) and/or (B), that the Relator has direct and independent knowledge of the information on which these allegations are based within the meaning of **31 U.S.C. §3730(e)(4)(A) and (B)** and has voluntarily provided the information to the Government before filing the Complaints which is based on the information provided by the Relator to the Government and the Relator is the original source.

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SECTION NO. 4

SYNOPSIS OF THE FALSE CLAIM SCHEME

4(A) BACKGROUND

35. In the United States, prescription drugs [REDACTED] are only provided or dispensed to patients upon the order of a physician.

36. Prescription drugs provided outside of the hospital setting are sold ordinarily by community retail pharmacies (i.e. Walgreens, Eckerd's and neighborhood independent drug stores) directly to the patient. Typically a patient is provided a prescription for a particular drug by a physician. The patient takes the prescription and independently decides at which pharmacy the prescription will be filled. Thus, the prescribing physician has no financial incentive or financial inducement to prescribe a particular drug or recommend a drug as the therapy of choice over that of a possible alternative therapy.

37. This case, however, focuses on a different and distinct type of pharmaceuticals which cannot be taken by mouth and generally are not self administered. The specified pharmaceuticals are generally administered to the patient by a professional (i.e. a nurse) intravenously, by injection or [REDACTED]. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

38. The specified pharmaceuticals at issue in this Second Amended Complaint are generally not available for sale at community retail pharmacies. In most cases, the specified pharmaceuticals are only available through a hospital (either inpatient or outpatient), a specialized physician or clinic operated by a group of physicians or a specialized pharmacy.

39. Specialized pharmacies such as the Relator are sometimes known as home infusion pharmacies, IV pharmacies or home IV pharmacies. Throughout the United States it is very common to have physicians associated directly or indirectly with specialized pharmacies. This association may be through an ownership interest, service as consultant or medical director, or other financial relationships. The Relator's pharmacy has three physician investors.

40. The DEFENDANT PHARMACEUTICAL MANUFACTURERS refer to these specialized pharmacies as "closed Pharmacies" or by a similar descriptive name which generally means the pharmacies are not open to the public.

41. The specified pharmaceuticals are ordinarily prescribed by specialized physicians for the treatment of people who are afflicted with various forms of [REDACTED]

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[REDACTED]

42. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

43. The specialized physicians are in a unique relationship with the DEFENDANT PHARMACEUTICAL MANUFACTURERS for the specified pharmaceuticals in this Second Amended Complaint in that the physicians are not only prescribing the specified pharmaceuticals, but also directly providing and administering or arranging for provision and administration of the specified pharmaceuticals.

44. The DEFENDANT PHARMACEUTICAL MANUFACTURERS have each acted to induce physicians to order the pharmaceuticals at issue in this case by falsely representing inflated price and cost information such as, but not limited to, direct prices, wholesale acquisition costs, published prices and average wholesale prices so that claims submitted to the Medicare and States' Medicaid Programs for these drugs will be paid to the physicians or specialized pharmacies in amounts that grossly exceed the reasonable amount permitted by law.

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4(B) SPECIFIC FACT PATTERNS

45. The false claim scheme of the DEFENDANT PHARMACEUTICAL MANUFACTURERS is typically implemented in the following specific fact patterns:

A. A DEFENDANT DRUG MANUFACTURER possesses a patented or formerly patented drug and the manufacturer desires to induce physicians to utilize the Manufacturer's drug for their patients. The DEFENDANT DRUG MANUFACTURER will knowingly reduce its true prices for the drugs but will make false representations of inflated cost and price information upon which Medicare and States' Medicaid claims will be approved and paid. The physician ordering the drug and submitting the claim will thus receive substantially more money for the drug than a reasonable amount and will thus be induced financially to order it for his or her patients.

B. Generic versions of a drug become available and compete with the "brand name" manufacturer that held the patent on the drug. The generic manufacturers sell the drug to physicians, clinics and specialty pharmacies at prices far below the price level reported by the brand manufacturer but make false representations of their drug's prices. Often, the false prices reported by the generic manufacturer exceed the already inflated price reported by the brand name manufacturer. As a result, physicians who must decide whether to order a particular drug and their clinics and specialty pharmacies receive payments from the Medicare and States' Medicaid Programs for claims of infusion and injectable drugs that far exceed their cost.

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C. Manufacturers of brand and generic drugs [REDACTED] will report false and fraudulent price and cost information to Medicare and State' Medicaid Programs and cause providers to receive unreasonably high payments for claims so that providers are induced to prescribe or administer the manufacturer's drug rather than an alternative drug or non-drug therapy.

4(C) SURROUNDING CIRCUMSTANCES

46. The false claim scheme perpetrated by the DEFENDANT PHARMACEUTICAL MANUFACTURERS is aided by circumstances which include, but are not limited to the following:

A. The [REDACTED] drugs [REDACTED] at issue in this case are generally perceived to be high priced and often are high priced during the time they are subject to a patent held by the brand name manufacturer.

B. Consumers are unable to price shop for the pharmaceuticals at issue in this case, as they do with pharmaceuticals purchased at community retail pharmacies.

C. The price and cost representations made by pharmaceutical manufacturers in general, including the DEFENDANT PHARMACEUTICAL MANUFACTURERS, for many other drugs bear a truthful relationship to their true prices and costs.

D. Patients who receive the specified pharmaceuticals are extremely ill and not in a position to question their physician's decision as to who will provide the

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specified pharmaceuticals, which manufacturer's pharmaceuticals to use or as to the amount claimed for providing the specified pharmaceuticals.

E. The patients and third party payers, including the Medicare and States' Medicaid Programs, are not aware of the prices actually paid for the specified pharmaceuticals by the physician, clinic or specialty pharmacy which presented the claim for payment. Pharmaceutical manufacturers conceal from the Medicare and States' Medicaid Programs price reductions occurring due to competition in the marketplace and falsely and fraudulently represent pharmaceutical prices that far exceed the truthful prices.

F. Federal Medicare regulations require that claims be paid at the lesser of an estimated amount based upon average wholesale price ("AWP") or actual acquisition cost (taking into consideration inventory cost and waste but including no profit on the pharmaceutical itself). The Medicare program has been unable to determine actual acquisition costs for the pharmaceuticals at issue in this case. Therefore, Medicare pays claims at the average wholesale price for single source patented drugs as represented by the manufacturer, and at the median average wholesale price, as represented by the manufacturers, for drugs with generic equivalents [REDACTED].

G. The States' Medicaid programs are required to pay claims for the specified pharmaceuticals by estimating the actual acquisition cost to the provider. Most states rely on the price and cost representations made by the manufacturer in determining the payment amount for the specific manufacturer's pharmaceuticals.

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H. Physicians, clinics and specialty pharmacies submitting claims to Medicare or States' Medicaid Programs for the pharmaceuticals at issue in this case are paid for their professional services which are separately reimbursable charges. Medicare and States' Medicaid programs are prohibited by law from paying and never intended to pay the grossly excessive amounts for the specified pharmaceuticals. Those in a position to increase utilization of the specified pharmaceuticals thus receive exorbitant sums of money in excess of the reasonable amounts provided by law, all due to the false price and cost representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS.

I. The DEFENDANT PHARMACEUTICAL MANUFACTURERS are prohibited by federal statute and regulation from making false or misleading representations about their pharmaceutical products, including false or misleading representations about prices or costs. However, the truth and accuracy of their representations about prices or costs have not been scrutinized by Government officials while other information disseminated about their pharmaceutical products is closely scrutinized by the Food and Drug Administration.

47. The DEFENDANT PHARMACEUTICAL MANUFACTURERS each occupy positions of privilege and trust in the United States because they develop new pharmaceutical products and produce life saving pharmaceuticals. In return, the Pharmaceutical Manufacturers benefit from patents on new pharmaceutical products that can be sold at prices, set by the manufacturers, that enable the manufacturers to enjoy huge profits above costs as an accepted inducement to develop the new pharmaceutical

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products. When patents expire and other manufacturers bring "generic" versions of the formerly patented drug to the market, prices ordinarily fall due to competition and due to the fact that the generic manufacturers did not expend the large sums of money on research and development as did the original brand manufacturers. Prices also fall when manufacturers compete against alternative therapies or when they reduce prices so that third party payers will cover their drug for payment. Due to the Relator's position in the industry, the Relator has been made privy to the truthful cost and price information that has been concealed from the Medicare and States' Medicaid Programs and has directly witnessed the methods employed by each of the DEFENDANT PHARMACEUTICAL MANUFACTURERS in carrying out the false and fraudulent claims schemes set out herein. The Relator has further witnessed the Medicare and States' Medicaid Programs incurring damages because the DEFENDANT PHARMACEUTICAL MANUFACTURERS concealed price reductions and instead created the illusion that the specified pharmaceuticals continued to be sold at the price levels commanded by brand manufacturers before the price reductions occurred resulting from competition.

48. The false claim scheme at issue occurs to date as evidenced by pricing representations made for the generic injectable drug "Acyclovir." The Brand name for Acyclovir is Zovirax manufactured by [REDACTED]. [REDACTED] reported 1996 sales of \$529,300,000.00 for Zovirax. On April 22, 1997 [REDACTED] Zovirax patent expired. Acyclovir is a anti-viral drug that is widely prescribed to persons who are suffering with the HIV disease. Prior to the patent expiration, VAC's wholesale cost for 1 gm of

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Zovirax was \$103.67 and its AWP was \$113.20 (a difference of 9%). Defendant ABBOTT was one of the first companies to announce distribution of a generic injectable Acyclovir. On or about February 19, 1997, Defendant ABBOTT set a true pre distribution price of \$70.00 for 1 gm (**Exhibit "1"**) which was approximately 30% less than [REDACTED] brand Zovirax. However ABBOTT fraudulently and falsely reported to Medical Economics (**Exhibit "2"**) and First Data Bank a Direct Price of \$160.00 for 1 gm which caused Medical Economics and First Data Bank to set a false and fraudulent AWP of \$190.00 for 1 gm or approximately 70% more than the Brand. Before ABBOTT could begin distribution of its generic injectable Acyclovir, another drug manufacturer announced distribution of a competing generic injectable Acyclovir at an initial price less than ABBOTT's. On or about April 28, 1997, ABBOTT reacted to the market conditions of price competition by lowering its true price to providers from \$70.00 to \$60.00 for 1 gm (**Exhibit "3"**). Despite ABBOTT's reduction in prices to providers, ABBOTT continued to publish its original grossly inflated false and fraudulent representations of cost and price (**Exhibit "4"**). During a telephone conversation between VAC's Bentley and an ABBOTT marketing/sales representative, on or about May 30, 1997, Bentley was informed that ABBOTT was committed to capturing market share by "widening the spread for providers" by lowering the true price while inflating the price represented to Medicare and Medicaid. The following charts contain the specific allegations demonstrating the Acyclovir fraud:

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BRAND					
COMPANY	DRUG	NDC	RED BOOK AWP	VEN-A-CARE COST	FLORIDA MEDICAID
[REDACTED]	Zovirax 500 mg	[REDACTED]	\$ 56.60	\$ 47.20	\$ 50.47083
[REDACTED]	Zovirax 1 gm	[REDACTED]	\$113.20	\$103.67	\$100.94059

VERSUS

GENERIC					
COMPANY	DRUG	NDC	RED BOOK "AWP" "DP"	VEN-A-CARE COST	FLORIDA MEDICAID
Abbott	Acyclovir Sodium 500 mg	00074-4427-01	\$95.00 \$80.00	\$35.00 \$30.00	\$ 84.5500
Abbott	Acyclovir Sodium 1,000 mg (1 gm)	00074-4452-01	\$190.00 \$160.00	\$70.00 \$60.00	\$169.1000

**4(D) AN EFFECT OF FALSE PRICING SCHEME AND RESULTING ILLEGAL
SPLIT FEE ARRANGEMENTS IS TO DRIVE LAW ABIDING
COMPETITORS OUT OF BUSINESS**

49. The actions of the DEFENDANT PHARMACEUTICAL MANUFACTURERS alleged herein result in grossly excessive amounts being paid to their customers by the Medicare and States' Medicaid Programs for claims submitted for the specified pharmaceuticals. Accordingly, the exorbitant payments induce physicians, clinics and

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specialty pharmacies to increase the utilization of the specified pharmaceuticals. The DEFENDANT PHARMACEUTICAL MANUFACTURERS were in a position to increase the utilization of their specified pharmaceuticals by causing an enormous concealed financial inducement to be unwittingly paid by the Medicare and Medicaid Programs to the DEFENDANT PHARMACEUTICAL MANUFACTURERS' customers, the physicians and specialized pharmacies. The financial inducement was so great for many of the specified pharmaceuticals at issue in this Second Amended Complaint that the profits derived from the provision of the specified pharmaceuticals greatly exceeded the physicians' professional fees and provided what can only be characterized as "windfall profits." In many markets, including the Relator's, specialty pharmacies and clinics are unable to compete unless they enter financial arrangements with prescribing physicians whereby the grossly excessive amounts paid by the Medicare and States' Medicaid Programs are split with the prescribing physicians. Over the last six (6) years, the Relator's business has all but been extinguished because of the Relator's refusal to benefit from the false and fraudulent claims schemes specified herein. The Relator has been unable to effectively compete with those physicians, clinics and specialty pharmacies who benefit from the DEFENDANT PHARMACEUTICAL MANUFACTURERS' false claims scheme because the financial inducement to the prescribing physicians often exceeds their compensation from the practice of medicine.

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4(E) FALSE PRICING SCHEME - "THE SPREAD"
Direct Benefits to Pharmaceutical Manufacturers -
Maximizing Sales Volume, Capturing Market Share
and Increasing Utilization of Products

50. The DEFENDANT PHARMACEUTICAL MANUFACTURERS benefit directly from their false pricing scheme of concealing their true prices while making grossly inflated false and fraudulent representations of prices and costs by maximizing their products' sales volume, capturing market share for their products, and increasing utilization of their products by providers. An example of how the DEFENDANT PHARMACEUTICAL MANUFACTURERS directly benefit from their false pricing scheme is demonstrated by data for the first quarter of 1997 from the State of Florida's Medicaid Program setting out Florida Medicaid's reimbursements paid to the customers of pharmaceutical manufacturers and utilization of their products by their customers for the drug [REDACTED]

[REDACTED].

51. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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52.

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[REDACTED]

[REDACTED]

[REDACTED]

53. Through the above described scheme of concealing their true prices and representing falsely inflated prices and costs, the DEFENDANT PHARMACEUTICAL MANUFACTURERS caused the States' Medicaid Programs and Medicare to pay kickbacks (illegal remunerations) from Federal and States' Governments' funds to the DEFENDANT PHARMACEUTICAL MANUFACTURERS' customers.

54. In many instances, the kickbacks paid from Governments' funds were in excess of 1,000% over the providers' true costs and over the reasonable reimbursement amounts which the Governments intended to pay. The grossly excessive profits have led to a proliferation of illegal split fee arrangements between the pharmaceutical manufacturers' customers and persons or entities who are in a position to refer patients. The split fee/kickbacks also serve as a financial inducement for the referrals of more patients and greater utilization of the products.

55. This case focuses on the specified pharmaceuticals manufactured by and/or distributed by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and sold either directly, through wholesalers or through group purchasing organizations to physicians, such as oncologists, hematologists and infectious disease physicians and others as well as the specialized "closed" pharmacies.

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56. The damages sought herein include, but are not limited to, those arising from the specific pharmaceuticals set out in Sections 8 through 29 and elsewhere throughout this Second Amended Complaint. The specific pharmaceuticals set out herein are alleged to meet the specificity required in pleading the claims alleged as required by law. The damages sought herein encompass all damages and penalties arising from the false claims relating to all pharmaceuticals of all sizes of the DEFENDANT PHARMACEUTICAL MANUFACTURERS about which false price and cost representations and records caused the presentment of false claims for payment and approval. These claims also encompass recovery of the funds paid due to the false and fraudulent claims, regardless of the person or entity that ultimately received the funds or from which the United States ultimately recovers the funds.

SECTION NO. 5

**BACKGROUND OF HOW UNITED STATES' MONIES
ARE PAID FOR PHARMACEUTICAL CLAIMS UNDER
"PART B" OF THE MEDICARE PROGRAM**

57. As one of its functions, HHS, through HCFA, provides health insurance benefits to aged and disabled Americans pursuant to the provisions of the Medicare program, **Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq.**

58. The Medicare program provides covered health care benefits to certain targeted populations such as those persons who are over age 65, persons who are disabled, and persons who have end stage renal disease.

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59. The Medicare program is divided into two distinct parts: (A) Medicare Part A (Hospital Insurance for the Aged and Disabled) which covers services and goods furnished by hospitals, home health agencies, hospices, and skilled nursing facilities; and (B) Medicare Part B (Supplementary Medical Insurance for the Aged and Disabled) which covers physician services, and a range of other noninstitutional services, such as durable medical equipment ("DME"), oxygen concentrators, diagnostic laboratory tests, X-rays, and certain limited pharmaceutical products and supplies.

60. This case focuses on the Medicare program's limited benefit for pharmaceuticals which are provided either (A) incident to a physician's service and cannot be self administered or (B) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. Because this limited pharmaceutical benefit is provided on an "incident to" a physician's service basis or in conjunction with the medical necessity of a DME device, Congress' statutes and the corresponding HHS regulations and HCFA policies have sought to limit Medicare's payments for claims for the pharmaceuticals at issue to a reasonable amount based upon the cost of the drug. This is due, in part, to the fact that the Medicare program is already paying for the physicians' professional fees and for the covered DME equipment. The exorbitant profits created by the DEFENDANT PHARMACEUTICAL MANUFACTURERS' false price and cost representations has totally thwarted the fundamental requirements of the Medicare Program and States' Medicaid Programs that payment of claims for the

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specified pharmaceuticals be limited to reasonable amounts to cover the added cost of the pharmaceuticals.

61. HCFA administers the Medicare program. HCFA awards cost-reimbursement contracts to private companies to evaluate and to process Medicare beneficiaries' claims for payment on behalf of HCFA. Under Part A, HCFA refers to contractors as "intermediaries". Under Part B, HCFA refers to contractors as "carriers" and durable medical equipment regional carriers ("DMERCs"). Under Part B, HCFA pays the carriers and the DMERCs to process claims for covered benefits supplied to eligible beneficiaries and to make payments to the providers or to the Medicare beneficiaries for the covered services rendered under Medicare Part B. **42 U.S.C. §1395(j) et. seq.**

62. Congress has mandated that the Medicare Program pay no more than eighty percent (80%) of the reasonable charge for Part B pharmaceutical claims from federal funds. **42 U.S.C. §1395(l) et seq.**

63. Medicare Regulation 42 CFR, §405.517, effective January 1, 1992, sets out the methodology to determine the reasonable charge for payment of claims for drugs. The methodology for single source drugs is based on the lower of estimated acquisition cost or the national average wholesale price of the drug. The methodology for multiple source drugs is based on the lower of the estimated acquisition cost or the wholesale price that is the median price for all sources of the generic form of the drug. This regulation provides instructions to be used by the Part B Carriers and DMERCs on how the estimated acquisition cost is to be determined. The instructions state that the estimated acquisition

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cost is to be based on surveys of actual invoice prices of drugs paid by the providers. The regulation also states that the Medicare Part B Carriers and DMERCs may consider such other factors as inventory, waste and spoilage in calculating the estimated acquisition cost of the drug but does not provide for profit on the drug itself. [REDACTED]

[REDACTED]

64. Part B pharmaceutical claims are submitted in one of two ways. The first is by submitting to the Part B carriers or DMERCs a completed (hard copy) HCFA 1500 Form. The second is through an electronic claims filing procedure whereby the same information required to be included on the hard copy HCFA 1500 Form is transmitted to the Medicare Part B carriers or DMERCs. Two HCFA 1500 Form versions were used during the time relevant to these proceedings. HCFA Form 1500 (1/84) was used by the Medicare program for Part B pharmaceutical claims filed on or after January, 1984. In or about December 1990, HCFA created HCFA Form 1500 (12/90) and required its use for pharmaceutical claims submitted on or after May 1, 1992. Either HCFA Form 1500 (12/90) or HCFA Form 1500 (1/84) could be used for Part B pharmaceutical claims from December, 1990 through April, 1992.

65. Providers submit claims for payment to the Medicare Program for the specified pharmaceuticals at issue in this case using HCFA's Common Procedure Coding System ("HCPCS"). The HCPCS system for pharmaceuticals is a 5 digit alphanumeric code, such as [REDACTED], 50 mg. = HCPCS Code [REDACTED].

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66. HCFA requires all Part B Carriers and the DMERCs to report to HCFA Central quarterly claims activity by HCPCS Code for all pharmaceuticals submitted by providers for reimbursement by the Medicare Program. This quarterly data collected by HCFA Central from all the Part B Carriers and the DMERCs is summarized in a report known as the Part B Extract and Summary System ("BESS") or Bess Reports.

67. Beneficiaries' claims are processed by the carriers as either "assigned", those claims for which payment is made directly to the provider, or "unassigned", those claims for which payment is made directly to the beneficiaries.

68. All or nearly all pharmaceutical claims for the charges at issue are made on an assigned basis.

69. Medical Economics, Inc., the Hearst Corporation and Medi Span are nationally recognized companies that specialize in gathering pharmaceutical wholesale and direct price data, and in publishing such information in such publications as "Drug Topics Red Book" (hereinafter referred to as the "Red Book") which is published by Medical Economics and the "Blue Book" which is published by the Hearst Corporation. The Hearst Corporation also, through its First Data Bank Division, provides an automated data base service containing pharmaceutical price and cost information.

70. The Relator's investigation has established that:

A. All of the Medicare Part B Carriers pay claims for the specified pharmaceuticals based on cost and price representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS as reported in the Red Book.

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B. All four DMERC's pay and approve claims for the specified pharmaceuticals based on cost and price representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS as reported in the Red Book.

C. The DEFENDANT PHARMACEUTICAL MANUFACTURERS regularly make representations of false price and cost information including AWP's directly to the Medicare Part B Carriers. By way of example, attached hereto and incorporated herein by reference as **Exhibits "5" and "6"** are copies of written representations of price and cost information provided or caused to be provided to the Medicare Carrier for the State of Florida by Defendants [REDACTED] and **Exhibit "7"** the Medicare Carrier for the State of Florida's memorandum of how it receives and utilizes price and cost representations of the Defendant [REDACTED].

D. The Medicare Carriers' initial efforts to survey physicians' actual invoice prices paid for pharmaceuticals to comply with the regulation 42 CFR §405.517 were stopped by a complaint filed by the American Society of Clinical Oncologists ("ASCO") with the Executive Office of Management and Budget asserting that the Paperwork Reduction Act had been violated. A subsequent effort by HCFA to design a new survey to determine physicians' actual invoice costs was also stopped by ASCO. ASCO complained that the actual prices being paid were discounts and confidential in nature and that the survey had other flaws.

E. Medical Economics, Inc. and The Hearst Corporation both rely solely upon the cost and price representations of the DEFENDANT PHARMACEUTICAL

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MANUFACTURERS for the pharmaceuticals specified in this Second Amended Complaint in establishing and reporting the DEFENDANT PHARMACEUTICAL MANUFACTURERS' AWP prices and direct prices.

71. This case focuses on the specified pharmaceuticals that are covered under Part B of the Medicare program which are sold and/or distributed by the DEFENDANT PHARMACEUTICAL MANUFACTURERS and for which the Medicare Part B carriers and the DMERCs rely on the cost and price representations reported by the DEFENDANT PHARMACEUTICAL MANUFACTURERS to pay and approve claims. The pharmaceuticals at issue in this case, for which Medicare has paid claims, include but are not limited to those specified in the following Table No. 1 together with their respective HCPCS codes. By way of example, the claim amount approved by Florida Medicare for each pharmaceutical in 1996 is compared with the Relator's cost in order to illustrate the grossly excessive payments resulting from the DEFENDANT PHARMACEUTICAL MANUFACTURERS false representations of price and cost.

TABLE NO. 1

1(A) DEFENDANT ABBOTT						
DRUG	NDC #	HCPCS CODE	1996 FLORIDA MEDICARE ALLOWABLE	1996 RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Sodium Chloride 0.9% 250 ml	00074-7983-02	J7050	\$9.43	\$0.95	\$8.48	892%
Sodium Chloride 0.9% 50 ml	00074-7983-03	J7040	\$10.14	\$0.95	\$9.19	967%

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1(A) DEFENDANT ABBOTT						
DRUG	NDC #	HCPCS CODE	1996 FLORIDA MEDICARE ALLOWABLE	1996 RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
Sodium Chloride 0.9% 1000 ml	00074-7983-09	J7030	\$11.06	\$1.03	\$10.03	973%
5% Dextrose in Water w/5% etoh 500 ml	00074-7922-03	J7060	\$9.98	\$0.96	\$9.02	939%
5% Dextrose in Water 1000 ml	00074-7922-09	J7070	\$11.23	\$1.12	\$10.11	902%
Dextrose 5% with Sodium Chloride 0.9% 500 ml	00074-7941-03	J7042	\$10.24	\$1.03	\$9.21	894%
Ringers Lactate 1000 ml	00074-7953-09	J7120	\$12.43	\$1.14	\$11.29	990%
Vancomycin HCL 500 mg	00074-4332-01	J3370	\$12.91	\$3.51	\$9.40	267%
Tobramycin Sulfate 80 mg	00074-3578-01	J3260	\$6.74	\$3.63	\$3.11	85%

[REDACTED]						
DRUG	NDC #	HCPCS CODE	1996 FLORIDA MEDICARE ALLOWABLE	1996 RELATOR'S COST	PROVIDER'S GROSS PROFIT \$	PROVIDER'S GROSS PROFIT %
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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**PAGES 41 THROUGH 52
HAVE BEEN COMPLETELY REDACTED**

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[REDACTED]						
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

72. For many of the specified pharmaceuticals, the DEFENDANT PHARMACEUTICAL MANUFACTURERS' false and fraudulent representations of price and cost caused the Medicare Program to pay and approve claims at such excessive amounts that the 20% co-payment paid by the patient exceeded the true price of the pharmaceuticals. Table No. 2 below lists some of those specified pharmaceuticals, the amount approved in 1996 by Florida Medicare, the 20% co-payment paid by the patient, and the true price paid by the Relator.

TABLE NO. 2

**DRUGS WHERE THE MEDICARE PROGRAMS'
20% CO-PAYMENT
EXCEEDS THE TOTAL PRICE OF THE DRUG**

Drug	HCPCS Code	1996 Florida Medicare Allowable	20% Co-Payment	1996 Relator's Cost
[REDACTED]	[REDACTED]	\$ 21.53	\$ 4.36	\$ 1.89
[REDACTED]	[REDACTED]	\$ 3.05	\$ 0.61	\$ 0.22

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Drug	HCPCS Code	1996 Florida Medicare Allowable	20% Co-Payment	1996 Relator's Cost
[REDACTED]	[REDACTED]	\$ 8.56	\$ 1.72	\$ 0.79
Sodium Chloride 0.9% 1000 ml	J7030	\$ 11.06	\$ 2.21	\$ 0.95
Sodium Chloride 0.9% 500 ml	J7040	\$ 10.14	\$ 2.03	\$ 0.79
5% Dextrose/ Sodium Chloride 0.9% 500 ml	J7042	\$ 10.24	\$ 2.05	\$ 0.78
Sodium Chloride 0.9% 250 ml	J7050	\$ 9.43	\$ 1.89	\$ 0.78
5% Dextrose in Water 500 ml	J7060	\$ 9.98	\$ 1.99	\$ 0.75
5% Dextrose in Water 1000 ml	J7070	\$ 11.23	\$ 2.25	\$ 0.95
Lacted Ringers 1000 ml	J7120	\$ 12.43	\$ 2.48	\$ 1.02
[REDACTED]	[REDACTED]	\$ 1.37	\$ 0.27	\$ 0.26
[REDACTED]	[REDACTED]	\$ 1.23	\$ 0.25	\$ 0.10
[REDACTED]	[REDACTED]	\$ 1.23	\$ 0.25	\$ 0.10
[REDACTED]	[REDACTED]	\$ 45.08	\$ 9.02	\$ 9.00
[REDACTED]	[REDACTED]	\$225.40	\$45.08	\$45.00

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Drug	HCPCS Code	1996 Florida Medicare Allowable	20% Co-Payment	1996 Relator's Cost
[REDACTED]	[REDACTED]	\$ 51.43	\$10.29	\$10.00
[REDACTED]	[REDACTED]	\$102.89	\$20.58	\$20.00
Etoposide 10 mg	J9181	\$ 14.20	\$ 2.84	\$ 1.65
Etoposide 100 mg	J9182	\$141.97	\$28.35	\$16.50
[REDACTED]	[REDACTED]	\$ 40.04	\$ 8.01	\$ 6.85
[REDACTED]	[REDACTED]	\$ 31.75	\$ 6.35	\$ 3.75
[REDACTED]	[REDACTED]	\$ 38.25	\$ 7.65	\$ 7.27

SECTION NO. 6

**BACKGROUND OF HOW UNITED STATES' MONIES
ARE PAID FOR PHARMACEUTICAL CLAIMS UNDER
THE STATES' MEDICAID PROGRAMS**

73. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to **Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq.**

74. Benefits for pharmaceuticals are optional but all states have opted to provide Medicaid pharmaceutical reimbursement coverage.

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75. The federal portion of state Medicaid payments, Federal Medical Assistance Percentage ("FMAP") is based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. By example, Florida's FMAP contributed by the United States in 1995 was 56.28%.

76. The States, United States Territories and the District of Columbia are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for federal funds for Medicaid expenditures. **42 U.S.C. §1396a(a)(30)(A).**

77. State Health Plans must, in part, provide for payment of claims for prescription pharmaceuticals pursuant to a formula approved by the Secretary of HHS which determines the maximum allowable claim amount for each pharmaceutical manufactured by each manufacturer whose prescription pharmaceuticals qualify for Medicaid reimbursement based upon an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR 447.331.

78. In order to comply with the requirements of 42 CFR 447.331 to estimate a provider's costs for specific pharmaceuticals, the States' Medicaid programs acquire and receive price and cost information from the DEFENDANT PHARMACEUTICAL MANUFACTURERS directly and indirectly from entities equipped to do specialized data collection.

79. Medical Economics, Inc. and the Hearst Corporation are nationally recognized companies that specialize in gathering pharmaceutical pricing and cost

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information including Average Wholesale Price ("AWP"), Wholesale Acquisition Cost ("WAC"), Direct Price ("DP"), Actual Acquisition Cost ("AAC") and Estimated Acquisition Cost ("EAC") and publishing such information in "The Red Book" which is published by Medical Economics and "The Blue Book" which is published by the Hearst Corporation. The Hearst Corporation also, through its First Data Bank Division, provides an automated data base service containing pharmaceutical price and cost information.

80. The Relator's investigation has shown that:

A. HCFA has approved approximately 38 state plans whose methodology for arriving at a provider's estimated AAC as required by 42 CFR 447.331 includes discounting a percentage off of the AWP prices as computed by or collected by and published by First Data Bank. This discounting ranges from Alaska, whose state formula is AWP minus 5%, to Michigan, whose state formula is AWP minus 13.5 - 15.1 %. Nineteen HCFA approved state formulas are on a basis of AWP minus 10%. Seven states formulas are WAC plus a percentage or an AWP discount/WAC hybrid. The State of Florida's formula is WAC plus 7%. The State of Delaware bases reimbursement on AAC. The balance of the states use a EAC/AWP discount mix. **Exhibit "8"** is a chart that sets out how each individual State arrives at its estimate of AAC.

B. More than 90% of the individual state Medicaid programs rely upon price and cost information supplied by the Hearst Corporation's First Data Bank service in setting reimbursement amounts for pharmaceuticals.

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C. Medical Economics, Inc. and The Hearst Corporation both rely solely upon the pricing information provided by the DEFENDANT PHARMACEUTICAL MANUFACTURERS for the drugs specified in this Second Amended Complaint in establishing or reporting the DEFENDANT PHARMACEUTICAL MANUFACTURERS' AWP, DP, EAC, AAC and WAC.

D. Regardless of whether a State's reimbursement methodology estimates a provider's actual acquisition cost pursuant to federal regulation 42 CFR 447.331 as WAC plus a percentage or AWP minus a percentage, the representations made by the DEFENDANT PHARMACEUTICAL MANUFACTURERS regarding their direct prices to First Data Bank, Medical Economics and directly to the States' Medicaid Programs are material for the establishment of reasonable reimbursements by the States' Medicaid Programs. The importance that Pharmaceutical Manufacturers represent truthful direct prices and how the representations of direct prices affect reimbursements in both States whose formula is WAC plus a percentage and States whose formula is AWP minus a percentage is demonstrated by the following example:

(i)

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(ii)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(iii)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

E. The DEFENDANT PHARMACEUTICAL MANUFACTURERS regularly make direct representations of false price and cost information directly to the various state Medicaid agencies that are relied upon in approving and paying claims. [REDACTED]

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[illegible][illegible]

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[REDACTED]

81. The Food and Drug Administration ("FDA") assigns National Drug Codes ("NDC") numbers to identify each individual manufacturer and their pharmaceuticals' strength and size. NDC numbers are eleven digits, with the first five digits identifying the manufacturer or labeler, the next four digits identifying the product and the last two digits identifying the package size.

82. Providers are required to utilize the FDA's NDC numbers when submitting claims for reimbursement for pharmaceuticals to the State Medicaid programs.

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83. The vast majority of States award cost-reimbursement contracts to private companies to evaluate and process Medicaid recipients' claims for payment. The States refer to these contractors as fiscal agents.

84. Pharmaceutical claims are submitted in one of two ways. The first is by submitting to the fiscal agent or state agency a completed (hard copy) pharmacy claim form. The second is through an electronic claims filing procedure whereby the same information required to be included on the hard copy is transmitted electronically to the Medicaid fiscal agent or state agency.

85. The DEFENDANT PHARMACEUTICAL MANUFACTURERS are each fully capable of making truthful representations about prices and costs of the specified pharmaceuticals and do so when it is economically beneficial to them.

86. The DEFENDANT PHARMACEUTICAL MANUFACTURERS each participated in the Medicaid rebate program mandated by the Omnibus Budget Reconciliation Act of 1990 ("OBRA '90") and thus were required to pay rebates to the State Medicaid programs based upon their average manufacturer's price ("AMP") for non-innovator multi-source pharmaceuticals (generics) or best price ("BP") single source innovator drugs (Brand) for the specified pharmaceuticals at issue in this case. The AMP rebate amount is currently 11% and the BP is currently a minimum of 17% or more based on a formula between the drug manufacturers' difference in AMP and BP. The method of calculating rebates, therefore, causes it to be in the economic interests of the

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DEFENDANT PHARMACEUTICAL MANUFACTURERS to report the lowest AMPs and Best Prices based on the data available to them.

The following examples demonstrate that the DEFENDANT DRUG MANUFACTURES are able to report accurate prices when they choose to:

■ [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]